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# TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number

To Be Assigned

0989883

Filing Date

October 23, 2001

First Named Inventor

Henry LAMPARSKI

Group Art Unit

To Be Assigned

Examiner Name

To Be Assigned

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Total Number Of Pages In This Submission

14 + 1  
REFERENCE

Attorney Docket No.

348022000501

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## ENCLOSURES (check all that apply)

☐ Fee Transmittal Form

☐ Assignment Papers  
(for an Application)

☐ After Allowance Communication to Group

☐ Fee Attached

☐ Drawing(s)

☐ Appeal Communication to Board of Appeals and Interferences

☐ Amendment / Reply

☐ Licensing-related Papers

☐ Appeal Communication to Group  
(Appeal Notice, Brief, Reply Brief)

☐ After Final

☐ Petition

☐ Proprietary Information

☐ Affidavits/declarations

☐ Petition to Convert to a Provisional Application

☐ Status Letter

☐ Extension of Time Request

☐ Power of Attorney, Revocation  
Change of Correspondence Address

☒ Other Enclosure(s) (please identify below):

☐ Express Abandonment Request

☐ Terminal Disclaimer

1. Form PTO-1449 + copy - 10 pages

2. 1 Reference

3. Return Receipt Postcard

☒ Supplemental Information Disclosure Statement - 3 pages

☐ Request for Refund

☐ CD, Number of CD(s) \_\_\_\_\_

☐ Certified Copy of Priority Document(s)

Remarks

☐ Response to Missing Parts/  
Incomplete Application

☐ Response to Missing Parts  
under 37 CFR 1.52 or 1.53

## SIGNATURE OF APPLICANT, ATTORNEY OR AGENT

Firm

Morrison & Foerster LLP, 755 Page Mill Road, Palo Alto, California 94304-1018

or

Individual Name

Debra J. Gaister (Registration No. 83,888)

Signature

*Debra J. Gaister*

Date

October 31, 2001

## CERTIFICATE OF MAILING BY "EXPRESS MAIL"

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*Tamara Alcaraz*  
Tamara Alcaraz

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PATENT  
Docket No. 348022000501

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*Tamara Alcaraz*  
Tamara Alcaraz

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#3

In the application of:

Henri LAMPARSKI et al.

Serial No.: To be assigned

Filing Date: October 23, 2001

For: ADENOVIRUS VECTORS SPECIFIC  
FOR CELLS EXPRESSING  
CARCINOEMBRYONIC ANTIGEN  
AND METHODS OF USE THEREOF

Examiner: To be assigned

Group Art Unit: To be assigned

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**SUPPLEMENTAL INFORMATION DISCLOSURE  
STATEMENT UNDER 37 C.F.R. § 1.97 AND § 1.98**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO-1449. Copy of document no. 7 is submitted herewith. However, copies of the documents numbered 1-6 and 8-74 were previously submitted in an Information Disclosure Statement and/or Office Action, directed to the related application Serial Number 09/033,555, filed March 2, 1998, and, accordingly, copies are not included herewith. This protocol conforms with 37 C.F.R. § 1.98(d) and M.P.E.P. 609(A)(2). The Examiner is requested to make these documents of record in the

application.

This Information Disclosure Statement is submitted:

- ☐ With the application; accordingly, no fee or separate requirements are required.
- ☒ Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required.
- ☐ After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
  - ☐ A fee is required. A check in the amount of \* is enclosed.
  - ☐ A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided below; accordingly, no fee is believed to be due.
- ☐ After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided below and a check in the amount of \* is enclosed.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided below and a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.

Applicants would appreciate the Examiner initialing and returning the Form PTO-1449, indicating that the information has been considered and made of record herein.

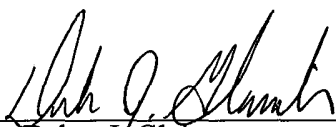
The information contained in this Information Disclosure Statement under 37 C.F.R. § 1.97 is to the best of my knowledge and is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by

third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

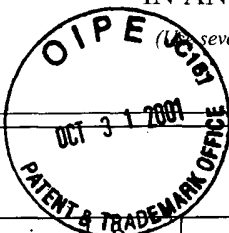
In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing **348022000501**. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: October 31, 2001

Respectfully submitted,

By:   
Debra J. Glaister  
Registration No. 33,888

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Form PTO-1449				Docket Number 348022000501		Application Number To Be Assigned	
<b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b> <small>(Use several sheets if necessary)</small>				Applicant <div style="text-align: center;">Henri LAMPARSKI et al.</div>			
				Filing Date October 23, 2001		Group Art Unit To Be Assigned	
				Date: October 31, 2001			
<b>U.S. PATENT DOCUMENTS:</b>							
Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
	1.	12/07/1999	5,998,205	Hallenbeck et al.			
	2.	12/16/1997	5,698,443	Henderson et al.			
<b>FOREIGN PATENT DOCUMENTS</b>							
Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES NO
	3.	05/04/1995	WO 95/11984	PCT			
	4.	05/26/1995	WO 95/14100	PCT			
	5.	06/06/1996	WO 96/17053	PCT			
	6.	11/07/1996	WO 96/34969	PCT			
	7.	01/16/1997	WO 97/01358	PCT			
	8.	08/13/1998	WO 98/35028	PCT			
<b>OTHER DOCUMENTS</b> <small>(including author, title, Date, Pertinent Pages, Etc.)</small>							
Examiner Initials	Ref. No.	Title					
	9.	Adair et al. "Targeted homologous recombination at the endogenous adenine phosphoribosyltransferase locus in Chinese hamster cells" <i>Proc. Natl. Acad. Sci. USA</i> (1989) <b>86</b> :4574-4578					
	10.	Arnberg et al. "Fiber Genes of Adenoviruses with Tropism for the Eye and the Genital Tract" <i>Viol.</i> (1997) <b>227</b> :239-244					
	11.	Bailey et al. "Cell Type Specific Regulation of Expression from the Ad40 E1B Promoter in Recombination Ad5/Ad40 Viruses" <i>Virology</i> (1994) <b>202</b> :695-706					
	12.	Bailey et al. "Enteric Adenovirus Type 40: Expression of E1B Proteins in Vitro and in Vivo" <i>Virology</i> (1993) <b>193</b> :631-641					
	13.	Behringer et al. "Dwarf mice produced by genetic ablation of growth hormone-expressing cells" <i>Genes &amp; Dev.</i> (1988) <b>2</b> :453-461					
	14.	Berkner et al. "Generation of adenovirus by transfection of plasmids" <i>Nucleic Acid Research</i> (1983) <b>11</b> (17):6003-6020					
	15.	Bett et al. "An efficient and flexible system for construction of adenovirus vectors with insertions or deletions in early regions 1 and 3" <i>Proc. Natl. Acad. Sci. USA</i> (1994) <b>91</b> :8802-8806					
	16.	Bett et al. "Packaging Capacity and Stability of Human Adenovirus Type 5 Vectors"					
EXAMINER:				DATE CONSIDERED:			
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Form PTO-1449		Docket Number 348022000501	Application Number To Be Assigned
INFORMATION DISCLOSURE CITATION PRIORITY APPLICATION (Use several sheets if necessary)		Applicant Henri LAMPARSKI et al.	
		Filing Date October 23, 2001	Group Art Unit To Be Assigned
		Date: October 31, 2001	
OTHER DOCUMENTS (including author, title, Date, Pertinent Pages, Etc.)			
Examiner Initials	No.	Title	
		<i>J. Virology</i> (1993) <b>67</b> (10):5911-5921	
	17.	Boulikas, Teni "Gene Therapy of Prostate Cancer: p53, Suicidal Genes, and Other Targets" <i>Anticancer Res.</i> (1997) <b>17</b> :1471-1505	
	18.	Braun et al. "Immunogenic Duplex Nucleic Acids Are Nuclease Resistant" <i>J. Immunol.</i> (1988) <b>141</b> (6):2084-2089	
	19.	Bridge et al. "Redundant Control of Adenovirus Late Gene Expression by Early Region 4" <i>J. Virol.</i> (1989) <b>63</b> (2):631-638	
	20.	Capecchi, Mario "Altering the Genome by Homologous Recombination" <i>Science</i> (1989) <b>244</b> :1288-1292	
	21.	Chang et al. "Cancer Gene therapy Using Novel Tumor specific Replication Competent Adenovirus Vectors" <i>Cold Spring Harbor Gene Therapy Meeting</i> (Sept. 1996)	
	22.	Chaturvedi et al. "Stabilization of triple-stranded oligonucleotide complexes: use of probes containing alternating phosphodiester and stereo-uniform cationic phosphoramidate linkages" <i>Nucleic Acids Res.</i> (1996) <b>24</b> (12):2318-2323	
	23.	<i>Current Protocols in Molecular Biology</i> (Ausubel et al., eds., 1987), Supp. 30, section 7.7.18, Table 7.7.1	
	24.	Felgner et al. "Cationic liposome-mediated transfection" <i>Nature</i> (1989) <b>337</b> :387-388	
	25.	Flint, S. J. "Regulation of Adenovirus mRNA Formation" <i>Advances in Virus Research</i> (1986) <b>31</b> :169-228	
	26.	Flint, S. J. "Expressions of Adenoviral Genetic Information in Productively Infected Cells" <i>Biochem. Biophys. Acta</i> (1982) <b>651</b> :175-208	
	27.	Frankel et al. "Selection and Characterization of Ricin Toxin A-Chain Mutations in <i>Saccharomyces cerevisiae</i> " <i>Mol. Cell. Biol.</i> (1989) <b>9</b> (9):415-42	
	28.	Goodrum et al. "The Early Region 1B 55-Kilodalton Oncoprotein of Adenovirus Relieves Growth Restrictions Imposed on Viral Replication by the Cell Cycle" <i>J. Virol.</i> (1997) <b>71</b> (1):548-561	
	29.	Graham, F. L. "Covalently closed circles of human adenovirus DNA are infectious" <i>EMBO J</i> (1984) <b>3</b> (12):2917-2922	
	30.	Graham, F. L. "Growth of 293 Cells in Suspension Culture" <i>J. Genetic Virology</i> (1977) <b>68</b> :937-940	
	31.	Graham et al. "A New Technique for the Assay of Infectivity of Human Adenovirus 5 DNA" (1973) <i>Virology</i> <b>52</b> :456-467	
	32.	Graham et al. "Characteristics of a Human Cell Line Transformed by DNA from Human Adenovirus Type 5" (1987) <i>J. Gen. Virol</i> <b>36</b> :59-72	
	33.	Grand, Roger "The structure and functions of the adenovirus early region 1 proteins" <i>Biochem. J.</i> (1987) <b>241</b> :25-38	
	34.	Hallenbeck, P.L. et al., "Novel Tumor Specific Replication Competent Adenoviral Vectors for Gene Therapy of Cancer" abstract no. O-36 <i>Cancer Gene Therapy</i> (1996) <b>3</b> (6):S19-S20.	
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	35.	Hauck et al. "Transcriptional regulation of the Carcinoembryonic Antigen Gene" <i>J. Biol. Chem.</i> (1995) <b>270</b> (8):3602-3610	
	36.	Hayashi et al. "Expression of a Thyroid Hormone-responsive Recombinant Gene Introduced into Adult Mice Livers by Replication-defective Adenovirus Can Be Regulated by Endogenous Thyroid Hormone Receptor" <i>J. Biol. Chem.</i> (1994) <b>269</b> (39):23872-23875	
	37.	Huber et al. "VDEPT: An enzyme/prodrug gene therapy approach for the treatment of metastatic colorectal cancer" <i>Adv. Drug Delivery Rev.</i> (1995) <b>17</b> :279-292	
	38.	Jaffe et al. "Adenovirus-mediated in vivo gene transfer and expression in normal rat liver" <i>Nat. Gent.</i> (1992) <b>1</b> :372-378	
	39.	Johnson et al. "Targeting of Nonexpressed Genes in Embryonic Stem Cells Via Homologous Recombination" <i>Science</i> (1989) <b>245</b> :1234-1236	
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	41.	Latimer et al. "Specificity of Monoclonal Antibodies Produced Against Phosphorothioate and Ribo Modified DNAs" <i>Mol. Immunol</i> (1995) <b>32</b> :1057-1064	
	42.	Le Gal Le Salle et al. "An Adenovirus Vector for Gene Transfer into Neurons and Glia in the Brain" <i>Science</i> (1993) <b>259</b> :988-990	
	43.	Mansour et al. "Disruption of the proto-oncogene int-2 in mouse embryo-derived stem cells: a general strategy for targeting mutations to non-selectable genes" <i>Nature</i> (1988) <b>336</b> :348-352	
	44.	Mastrangeli et al. "Diversity of Airway Epithelial Cell Targets for in Vivo Recombinant Adenovirus-mediated Gene Transfer" <i>J. Clin. Invest.</i> (1993) <b>91</b> :225-234	
	45.	Maxwell et al. "Cloning, Sequence Determination, and Expression in Transfected Cells of the Coding Sequence for the tox 176 Attenuated Diphtheria Toxin A Chain" <i>Mol. Cell. Biol.</i> (1987) <b>7</b> :1576-1579	
	46.	McKinnon et al. "Tn5 mutagenesis of the transforming genes of human adenovirus type 5" <i>Gene</i> (1982) <b>19</b> :33-42	
	47.	Messing et al. "P <sub>0</sub> Promoter Directs Expression of Reporter and Toxin Genes to Schwann Cells of Transgenic Mice" <i>Neuron</i> (1992) <b>8</b> :507-520	
	48.	Nevins, Joseph "Mechanisms of Viral-mediated Trans-activation of Transcription" <i>Adv. Virus Res.</i> (1989) <b>37</b> :35-83	
	49.	Osaki et al. "Gene therapy for Carcinoembryonic Antigen-producing Human Lung Cancer Cells by Cell Type-specific Expression of Herpes Simplex Virus Thymidine Kinase Gene" (1994) <i>Cancer Res.</i> <b>54</b> :5258-5261	
	50.	Palmiter et al. "Cell Lineage Ablation in Transgenic Mice by Cell-Specific Expression of a Toxin Gene" <i>Cell</i> (1987) <b>50</b> :435-443	
	51.	Peyrottes et al. "Oligodeoxynucleoside phosphoramidates (P-NH <sub>2</sub> ): synthesis and thermal stability of duplexes with DNA and RNA targets" <i>Nucleic Acids Res.</i> (1996) <b>24</b> (10):1841-1848	
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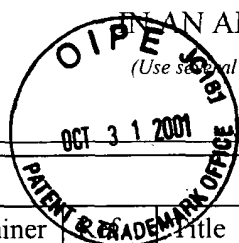


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	52.	Piatak et al. "Expression of Soluble and Fully Functional Ricin A Chain in Escherichia coli Is Temperature-sensitive" <i>J. Biol. Chem.</i> (1988) <b>263</b> (10):4837-4843	
	53.	Quantin et al. "Adenovirus as an expression vector in muscle cells in vivo" <i>Proc. Natl. Acad. Sci. USA</i> (1992) <b>89</b> :2581-2584	
	54.	Ragot et al. "Efficient adenovirus-mediated transfer of a human minidystrophin gene to skeletal muscle of mdx mice" (1993) <i>Nature</i> <b>361</b> :647-650	
	55.	Richards et al. "The transcriptional control region of the human carcinoembryonic antigen gene: DNA sequence and homology studies" <i>DNA Seq.</i> (1993) <b>4</b> :185-196	
	56.	Richards et al. "Transcriptional Regulatory Sequences of Carcinoembryonic Antigen: Identification and Use with Cytosine Deaminase for Tumor-Specific Gene Therapy" <i>Human Gene Ther.</i> (1995) <b>6</b> :881-893	
	57.	Rosenfeld "Adenovirus-Mediated Transfer of a Recombinant $\alpha$ 1-Antitrypsin Gene to the Lung Epithelium in Vivo" <i>Science</i> (1991) <b>252</b> :431-434	
	58.	Rosenfeld et al. "In Vivo Transfer of the Human Cystic Fibrosis Transmembrane Conductance Regulator Gene to the Airway Epithelium" <i>Cell</i> (1992) <b>68</b> :143-155	
	59.	Schrewe et al. "Cloning of the Complete Gene for Carcinoembryonic Antigen: Analysis of Its Promoter Indicates a Region Conveying Cell Type-Specific Expression" <i>Mol. Cell. Biol.</i> (1990) <b>10</b> (6):2738-2748	
	60.	Schultz et al. "Oligo-2'-fluoro-2'-deoxynucleotide N3'→P5' phosphoramidates: synthesis and properties" <i>Nucleic Acids Res.</i> (1996) <b>24</b> (15):2966-2973	
	61.	Stratford-Perricaudet "Evaluation of the Transfer and Expression in Mice of an Enzyme-Encoding Gene Using a Human Adenovirus Vector" <i>Human Gene Therapy</i> (1990) <b>1</b> :241-256	
	62.	Stratford-Perricaudet et al. "Widespread Long-term Gene Transfer to Mouse Skeletal Muscles and Heart" <i>J. Clin. Invest</i> (1992) <b>90</b> :626-630	
	63.	Swaminathan et al., "Regulation of Adenovirus E2 Transcription Unit" <i>Curr. Topics in Micro. and Imm.</i> (1995) <b>199</b> (part 3):177-194	
	64.	Takiff et al. "Propagation and In Vitro Studies of Previously Non-cultivable Enteric Adenoviruses in 293 Cells" <i>Lancet</i> (1981) <b>11</b> :832-834	
	65.	Tanaka et al. "Adenovirus-mediated Prodrug Gene Therapy for Carcinoembryonic Antigen-producing Human Gastric Carcinoma Cells in Vitro" <i>Cancer Res.</i> (1996) <b>56</b> :1341-1345	
	66.	Tollefson et al. "The 11,600- $M_w$ Protein Encoded by Region E3 of Adenovirus Is Expressed Early but Is Greatly amplified at Late Stages of Infection" <i>J. Virol.</i> (1992) <b>66</b> (6):3633-3642	
	67.	Tollefson et al. "The Adenovirus Death Protein (E3-11.6K) Is Required at Very Late Stages of Infection for Efficient Cell Lysis and Release of Adenovirus from Infected Cell" <i>J. Virol.</i> (1996) <b>70</b> (4):2296-2306	
	68.	Verma et al. "Gene therapy- promises, problems and prospects" <i>Nature</i> (1997) <b>389</b> :239-242	
	69.	Virtanen et al. "mRNAs from Human Adenovirus 2 Early Region 4"	
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Applicant

Henri LAMPARSKI et al.

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## OTHER DOCUMENTS

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Examiner Initials	Ref. No.	Title
		<i>J. Virol.</i> (1984) <b>51</b> (3): 822-831
	70.	Wang et al. "Expression of the APRT Gene in an Adenovirus Vector System as a Model for Studying Gene Therapy" <i>Adv. Exp. Med. Biol.</i> (1991) <b>309B</b> :61-66
	71.	Weinberg et al. "A cell line that supports the growth of a defective early region 4 deletion mutant of human adenovirus type 2" <i>Proc. Natl. Acad. Sci.</i> (1983) <b>80</b> :5383-5386
	72.	Willcocks et al. "Characterization of the Genomic Organization of Human Carcinoembryonic Antigen (CEA): Comparison with Other Family Members and Sequence Analysis of 5' Controlling Region" <i>Genomics</i> (1990) <b>8</b> :492-500
	73.	Zhai et al. "A Nude Mouse Model for the In Vivo Production of Hepatitis B Virus" <i>Gastroenter.</i> (1990) <b>98</b> :470-477
	74.	Zijlstra et al. "Germ-line transmission of a disrupted $\beta_2$ -microglobulin gene produced by homologous recombination in embryonic stem cells" <i>Nature</i> (1989) <b>342</b> :435-438

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